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# Miniaturized digital camera system for disposable endoscopic applications

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## 1. Introduction

Standard screening procedures of the gastrointestinal tract adopted since few years ago and still widely diffused today are based on the use of a flexible endoscope which includes a light delivery system, an imaging camera and some additional channels for medical purposes. Light from an external source is carried to the target through an optical fiber and the images of the observed tissue are transferred back through a bundle of coherent optical fibres or a lens system to an acquisition camera located outside the body. Image is thus displayed on a video for diagnostic purposes. Commercial video gastroscopes have a diameter of 9-12 mm and a length of 110 cm, while video colonoscope has a high diameter till 13 mm and a length from 70 to 160 cm. These instruments are inserted into the human body through the mouth or the anus to assess the interior surfaces of the stomach and the colon, respectively. Generally these medical procedures are carried out while the patient is awake. Despite the reduction in the diameter of the instrument and the improvement in terms of flexibility and other features, the procedure is still painful, therefore local anesthesia (e.g. for gastroscopy) or even sedation (for colonoscopy) are required for some patients [1,2].

Due to the difficulty to reach the small bowel by mean of a standard gastroscope, pathologies of this gastrointestinal tract, such as Crohn's disease or obscure gastrointestinal bleeding, need dif-

# ABSTRACT

A miniaturized color camera module for disposable endoscopic applications and minimally invasive surgery has been designed and developed. The module consists of a Complementary Metal Oxide semiconductor (CMOS) sensor, miniaturized optics, a Light Emitting Diode (LED)-based illuminator and a connector on a single substrate. The compact size  $(5.0 \text{ mm} \times 8.2 \text{ mm} \times 7.0 \text{ mm})$ , high-efficiency illumination, VGA resolution and good image quality allow it to be used in endoluminal procedures. A demonstration system has been built and tested *in vivo*. The module is connected through a 1.5-m long cable to a receiver board, which transfers the data stream to a Personal Computer (PC). A dedicated software controls the hardware setting and displays the image, after having performed various color and image processing tasks.

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ferent kinds of examination, named push enteroscopy or double balloon enteroscopy. Push enteroscopy is an invasive procedure where a longer and more rigid gastrointestinal endoscope, known as push enteroscope, is introduced, into the upper gastrointestinal tract to examine and evaluate the proximal section of the small bowel [3]. Double balloon enteroscopy is a newly developed endoscopic method allowing exploration of the small intestine in steps by using two balloons to grip the intestinal wall; the endoscope can be inserted for 430 cm inside the small bowel [4]. These procedures are invasive, cause high discomfort to the patient and need to be performed under general anesthesia.

The advent of video capsule endoscopy (VCE) in year 2000 has dramatically changed the diagnosis and management of many disease of the small intestine, turning inspection of the gastrointestinal tract into non-invasive and almost completely painless examination [5,6].

# 1.1. The endoscopic capsule

The endoscopic capsule (EC) is a small device with the size and shape of an antibiotic pill which is easily swallowed by the patient and transmits the images during its transit through the gastrointestinal tract. These features permit, for example, to investigate the entire small bowel with benefits in terms of patient comfort and reduced risk of side effects. The main building elements of an EC are an imaging sensor with lens and light-source (the camera module), a battery, a wireless module for data exchange and some glue electronics. All these parts are contained in a bio-compatible enclosure (with a transparent window), suited to withstand the conditions of

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the bowels. Beside of the basic functionality, some advanced features have been recently introduced. It is worth to mention a drug reservoir for targeted delivery of an active principle, pH and temperature sensors for monitoring of relevant parameters, actuators enabling active locomotion [7,8].

Despite of these innovations, the camera module remains the heart of the EC. Its design specifications are partially influenced by the biological environment which the capsule is targeted to. For example, the examination of the oesophagus is very fast and requires a high frame rate and a wide field of view, while the transit through the intestine lasts for many hours and an accordingly long lasting battery is necessary [9,10]. The requirements of low power consumption, good image quality and small size have to be met for any application. Low cost of the module is mandatory in case of a disposable application such as an endoscopic capsule. Considering these purposes, a camera module based on a commercial complementary metal oxide semiconductor (CMOS) color imager was developed and any component or technology used was selected on the basis of its contribution to the achievement of the mentioned requirements. A demo system was set up to evaluate a preliminary wired prototype of the module, which was successfully tested during ex vivo and in vivo experiments on a porcine model.

# 2. System overview

# 2.1. Camera module

The camera module prototype (Fig. 1(a)) is based on a commercial CMOS color imager. A device already available on the market was chosen to reduce development costs. VGA image resolution (640 × 480 pixels) with 2.2  $\mu$ m pixel size results in an active area of 1.1 mm × 1.4 mm in size. Pin count is limited by the use of serial data bus according to I<sup>2</sup>C protocol on input and standard mobile imaging architecture (SMIA) protocol on output [11]. Long-range signal integrity for the image stream is guaranteed by the use of impedance-matched low-voltage differential signaling (LVDS) lines. Among the various packaging options available, the die form



**Fig. 1.** The first prototype of the camera module, with its size compared to a  $\in 1$  cent coin (a). A detail of camera cable (b).

# Table 1

Features of image sensor.

Parameter	Value	
Optical format	1/11-in. VGA (4:3)	
Active area size	1.43mm  imes 1.07mm	
Die size	2.46mm  imes 2.73mm	
Active pixels count	648  imes 488	
Pixel size	$2.2\mu\text{m}$ $ imes$ $2.2\mu\text{m}$	
Color filter array	RGB Bayer pattern	
Frame rate	Programmable up to 30 fps	
Responsivity	1.1 V/lux s	
Dynamic range	64 dB	
Signal to noise ratio (max)	> 36.5 dB	
Power consumption	80 mW	

## Table 2

Features of camera module.

Parameter	Value
Dimension	5.0mm  imes 8.2mm  imes 7.0mm
Power consumption	190 mW max
Number of connection	12
Data output rate	140 Mbps
Image data output protocol	SMIA LVDS
Control data input protocol	I <sup>2</sup> C
Master clock	16-24 MHz
Field of view	60°
Lens f/#	2.8
LED luminous efficiency	46 lm/W

was selected to adopt a chip-on-board assembly technology. In this approach the die is attached on a printed circuit board (PCB) substrate and its signal pads are wire-bonded on the PCB tracks. Three high-efficiency (46 lm/W) white LEDs with small PCB footprint (0603) provide the proper amount of light. A low-cost plastic molded lens focus the image on the sensor with a field of view (FOV) of 60° (diagonal). Electrical connectivity is limited to power supply, system clock, high-speed image transfer (140 Mbps LVDS) and low-speed system control (I<sup>2</sup>C bus), with an overall count of 12 lines. Overall power consumption is limited to 190 mW with LEDs at full power and imager working at 30 frames per second. The main features of both the imaging sensor and the camera module are summarized in Tables 1 and 2.

The module is  $5.0 \text{ mm} \times 8.2 \text{ mm} \times 7.0 \text{ mm}$ , including optics, illumination and connector. It is worth to observe that the height of the module is dominated by the connector. The used component was selected for an easy connection of the prototype with a 0.5 mm pitch flat flexible PCB where a 24 MHz oscillator and the 12 wire of the cable are soldered (Fig. 1(b)).

In order to better quantify the contribution of the presented camera module, it is meaningful to compare its performance with the PILLCAM SB2, which can be considered the gold standard for capsule endoscopy (Table 3). The lightning system of the camera module is made up of 3 high-efficiency LEDs soldered to the same PCB where the imaging sensor is attached on. Because of a careful design, no shadows or illumination non-uniformities are caused by the asymmetrical layout around the optical axis and the lower position relative to the lens top. These two features allow the use of a single board, lowering the cost and simplifying the

# Table 3 A comparison between the proposed camera module and PILLCAM SB2.

	Camera module	PILLCAM SB2
Frontal dimension (diameter)	10.5 mm	11 mm
Optical system	1 lens	3 lenses
Field of view	60°	156°
Resolution	640  imes 480	256  imes 256
Number of LED	3	6



Fig. 2. Hardware architecture of the demonstration system.

assembly process. The camera module has overall dimensions of  $5.0 \text{ mm} (w) \times 8.2 \text{ mm} (h)$  which fits in a capsule with a minimum inner diameter of 9.6 mm. Thanks to its rectangular shape, an empty space of about 29 mm<sup>2</sup> is left free for future integration of specific tools, such as biopsy needles.

The optical system of the PILLCAM SB2 has a diameter of 11 mm. It is made up of 3 lenses (1 focusing lens and 2 field lenses), an aperture stop and the illumination sources, which are positioned behind a transparent elongated dome [12]. The combination of these elements leads to a 156° (diagonal) FOV. The optical system of the presented camera module is composed by a short-focal-length lens which focuses the light ray onto the optical sensor, achieving a FOV of 60° (diagonal). In order to preliminary evaluate the presented module during *ex vivo* and *in vivo* tests, a transparent Poly-methyl methacrylate (PMMA) window was placed in front of the system to protect the camera from organic material. However, a dome to be coupled with the present lens is under design. It will acts as a negative lens by using a different radius of curvature for the outer and inner surface. This dome will enable the system to achieve a FOV of 156° (diagonal).

### 2.2. Demonstration system

A demonstration system (Fig. 2) was built to verify the performance of the camera module in the realistic environmental conditions of *in vivo* experiments. For these preliminary tests, the camera module was wired through a 1.5-m long cable (with a diameter of 4 mm) to a custom receiver board (Fig. 3). The serial image data stream is decoded by a SMIA receiver interfaced to a Xilinx Virtex5 field programmable gate array (FPGA). The FPGA stores the



Fig. 3. Demonstration system.

stream into a double data rate synchronous dynamic random access memory /DDR2 SDRAM) used as a video buffer. The raw image is transferred to a host computer using a USB 2.0 host-client interface. Through this link, the computer sends to the board the values to be written into imager registers, the power level to be set for the LED driver and other low-level settings. A specifically developed software (Fig. 4) runs on the host PC, allowing the user to control the main high-level hardware settings (integration time, color channels gain, LED power, etc.). The software handles also the data stream from the camera module and performs a series of image processing tasks on the received raw data before displaying



Fig. 4. Software architecture of the demonstration system.



Fig. 5. Acquired images during ex vivo tests in porcine stomach.

them on video. The quality of the displayed image depends on the effectiveness of the implemented algorithms and on a fine tuning of their numerical parameters. The main processing tasks are:

- *Bayer pattern demosaicing.* Restoration of the color information missing due to the Bayer color filter pattern applied on the pixel matrix (demosaicing). The use of a first neighboring interpolating gradient-sensitive algorithm reduces artifacts which can appear along a sharp edge in the image. Computational complexity is slightly increased, if compared to other simple interpolating solutions, but leads to considerably better color rendering of tissue details.
- Lens vignetting correction. Compensation of the illumination nonuniformity caused by lens vignetting. Light shading at the



Fig. 6. In vivo experiments of the camera module.

image corners is removed by rescaling each pixel value using correction coefficients. The coefficients are lens-depending and are obtained with a calibration procedure on a reference image, based on a best-fit procedure with a two-dimensional second-order polynomial model.

- Bad pixel removal. Removal of the so-called 'hot pixels', which are pixels appearing white regardless of light conditions. This malfunctioning is due to tolerances in the chip manufacturing process and it is corrected by means of a median spatial filtering based on a 3 × 3 pixel kernel.
- White balance. A procedure consisting in a global adjustment of the intensities of the colors so that objects which appear white in the scene are rendered white in the image. The adjustment is carried out using a 9-coefficient matrix obtained from a calibration procedure with a 24-patch MacBeth ColorChecker target. Coefficients are calculated with a white-point-preserving least-square regression routine, which minimizes the difference between the acquired RGB coordinates of the patches and their reference values. White point is then adjusted on the basis of the knowledge of the LED chromatic coordinates in the CIE1931 color space [13].
- *Edge enhancement*. This step is based on a spatial filter with a Sobel  $3 \times 3$  pixel kernel, which enhances edge transitions. The main effect of this filtering is to make details to appear sharper. Ideally, uniform regions are left unchanged but a common drawback is the increase of their noise level. This unwanted effect is avoided in the implemented version, where the filtering is applied only where an edge has been previously detected [14].
- Gamma correction. Image data are converted to the standard RGB color space, used by the Microsoft Windows operating system to drive the monitor. This step includes the application of the gamma shift, which takes into account the non-linear sensitivity of the human eye to variation of luminance levels.



Fig. 7. Acquired images during in vivo tests.

The described flux guarantee a good rendering of the finest image details and, together with a calibrated monitor, an accurate color matching between the observed tissue and the displayed image. The version developed for the demonstration system is implemented in C++ language. The computational complexity of the algorithms and the high-level programming language imply the use of a high-performance PC to obtain images streaming at 30 frames per second.

# 3. Experimental results

Image quality was tested in *ex vivo* trials, in order to tune the hardware and software setting of the system. Some freshly excised porcine gastric tissues were used to acquire images (Fig. 5). Once the correct parameter settings were defined, *in vivo* experiments were performed on a porcine model. The aim of these trials was to test the performance of the camera module by evaluating the effectiveness of illumination as well as the image quality in a realistic environment.

The experiments were carried out in a specialized experimental animal facility, with the assistance and collaboration of a specially trained medical team in compliance with the regulatory issues related to animal experiments. The camera module was located in a capsular shell with size of 13 mm (diameter)  $\times$  20 mm (length) manufactured with rapid prototyping printing, while a PMMA slide was placed in front of the camera module. In order to avoid misting

up due to temperature gradient the slide was coated with a anti-fog coating. Additionally a hydrophobic coating was sprayed to prevent the deposit of organic material.

The capsule was introduced in the stomach through a 5 mm laparotomic incision (Fig. 6) and manually oriented to visualize the most interesting regions of the gastric cavity. The light level was regulated by software in order to achieve the best quality of the image displayed on the PC. A video was recorded for the average duration of a detailed gastroscopy (30 min), and two of its frames are shown in Fig. 7. Another test was performed introducing the capsule in the colon, through the anus, in order to reproduce a colonoscopy. The analysis of the acquired movie indicates that the proposed camera module is able to evenly illuminate the inner tissue, with a light level suitable to obtain low-noise images. The good focusing and color rendition allow the features of the observed target to be properly displayed, thus enabling the endoscopist to reliably perform a diagnosis.

A comparison on two images acquired by the camera module and the PILLCAM SB2 during in vivo tests has been carried out. The amount of light provided by the designed illumination system is comparable with a PILLCAM SB2 image taken in similar conditions (Fig. 8). From an illumination viewpoint, images obtained with the PILLCAM SB2 and the presented module are comparable, but with half the number of LEDs, half the footprint and, with a reasonable confidence, half the power consumption. This result is obtained through a careful selection of high-efficiency LEDs and a high sensitivity camera. Since no images with reference targets are available for the PILLCAM SB2, a comparison on two images acquired during in vivo tests has been carried out. A  $40 \times 40$  pixels region without textures or features related to the observed target and with an even illumination was identified and selected in each image. The histogram of the pixel code distribution was calculated (Fig. 9). As resulting from the pictures, the selected regions have the same



Fig. 8. Acquired image from PILLCAM SB2 (a) and from camera module (b).



**Fig. 9.** Histogram of PILLCAM SB2 image selected region (a) and of the proposed camera module selected region (b).

mean value even if the PILLCAM SB2 illumination system is composed by 6 LEDs while the presented camera module has only 3 LEDs. Assuming that the two targets have a comparable reflectivity, this result could be achieved by the use of different integration times in the two imaging sensors and by adjusting the output power of the two lightning system. Moreover, the standard deviation of the PILLCAM SB2 histogram is higher than the one obtained from the flat region of the image taken with the presented camera module. This means a lower fixed pattern noise (FPN) for the presented module.

## 4. Conclusions and future work

The small size achieved makes the module easily fitting into a swallowable capsule and the overall power consumption allows for battery-supplied operation. The quality of acquired images in terms of resolution and color rendition is good, as required by the physicians to perform correct and reliable diagnosis, while low cost of the chosen components and technologies allows the module to be used in disposable applications. The prototype was successfully tested during *ex vivo* and *in vivo* experiments on a porcine model.

A new version of the camera module is currently under development. It will have a smaller size and a wireless interface and will be tailored on an endoscopic capsule. The image processing algorithm is going to be ported from C++ language to VHDL code for an implementation on FPGA device. The PC computational load will be therefore greatly reduced allowing lower-end computers to be used to display the image stream.

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#### **Biographies**

**Daniele Covi** graduated in physics (summa cum laude) from the University of Trento (Italy) in 2001 working on the active control of magnetic fields for atomic traps. In 2005 he received the MBA from the Alma Graduate School – University of Bologna (Italy). He joined Neuricam in 2000 participating in the design and transfer to production of CMOS optical sensors and setting up the Electro-Optical Laboratory for imaging sensors characterization. He was head of the VLSI Design Area since 2002. He is currently working as project manager in the field of advanced electro-optical systems design. His research interests focus on optical distance measurement systems and miniaturized camera modules for endoscopy applications.

**Carmela Cavallotti** received her Laurea Degree in Biomedical Engineering (with Honors) from the Campus Bio-Medico University in Rome in December 2007. Currently she is a Ph.D. student in Biorobotics at the CRIM Lab of the Scuola Superiore Sant'Anna in Pisa.

**Monica Vatteroni** was born in La Spezia, IT, in 1975. She received the M.S. degree in electrical engineering from University of Pisa, Pisa, IT, in 2001 and PhD degree in Physics from the University of Trento, Trento, IT, in 2008. From 2002 to 2008, she worked at NeuriCam, Trento, IT, as Pixel Engineer and analog designer, becoming responsible for CMOS Image Sensor development in 2005. Presently she is working at Scuola Superiore Sant'Anna, Pisa, IT, as post-doctoral fellow where she is responsible for research and development of image sensors and vision systems for biomedical applications. She is the author or coauthor of a few conference and journal publications and three patents. Her interests include CMOS image sensors, low-noise analog electronics, high dynamic range pixels and endoscopic vision systems.

**Luca Clementel** received the B.S. degree in communication engineering from the University of Trento in 2001 developing a digital neural network implemented in FPGA. He joined Neuricam Srl, Trento, in 2001, where he designed digital architectures in programmable logic devices for vision systems like glue logic for demonstration baseboards of optical sensors and complex image processing algorithms. He is currently an HDL developer and a project manager in the field of intelligent vision systems design.

**Pietro Valdastri** received his Laurea Degree in Electronic Engineering (with Honors) from the University of Pisa in February 2002. In the same year he joined the CRIM Lab of the Scuola Superiore Sant'Anna in Pisa as Ph.D. student. In 2006 he obtained his Ph.D. in Bioengineering from Scuola Superiore Sant'Anna by discussing a thesis titled "Multi-Axial Force Sensing in Minimally Invasive Robotic Surgery". He is now assistant professor at CRIM Lab, with main research interests in the field of implantable robotic systems and active capsular endoscopy. He is working on several European projects for the development of minimally invasive and wireless biomedical devices.

Arianna Menciassi received her Laurea Degree in Physics (with Honours) from the University of Pisa in 1995. In the same year, she joined the CRIM Lab of the Scuola Superiore Sant'Anna in Pisa as a Ph.D. student in Bioengineering with a research program on the micromanipulation of mechanical and biological micro objects. In 1999, she received her Ph.D. degree by discussing a thesis titled "Microfabricated Grippers for Micromanipulation of Biological and Mechanical Objects". Currently she is a professor of biomedical robotics at the Scuola Superiore Sant'Anna, Pisa. Her main research interests are in the fields of biomedical micro and nano-robotics, microfabrication technologies, micromechatronics and microsystem technologies. She is working on several European projects and international projects for the development of micro and nano-robotic systems for medical applications.

Paolo Dario received his Laurea Degree in Mechanical Engineering from the University of Pisa in 1977. Currently, he is a professor of biomedical robotics at the Scuola Superiore Sant'Anna, Pisa. He also established and teaches the course on Mechatronics at the School of Engineering, University of Pisa. He has been a visiting professor at the Ecole Polytechnique Federale de Lausanne (EPFL), Lausanne, Switzerland, and at Waseda University, Tokyo, Japan. He is the director of the CRIM Lab of Scuola Superiore Sant'Anna, where he supervises a team of about 70 researchers and Ph.D. students. His main research interests are in the fields of medical robotics, mechatronics and microengineering, and specifically in sensors and actuators for the above applications. He is the coordinator of many national and European projects, the editor of two books on the subject of robotics and the author of more than 200 journal papers. He is a member of the Board of the International Foundation of Robotics Research. He is an associate editor of the IEEE Transactions on Robotics and Automation, a member of the Steering Committee of the Journal of Microelectromechanical Systems and a guest editor of the Special Issue on Medical Robotics of the IEEE Transactions on Robotics and Automation. He serves as president of the IEEE Robotics and Automation Society and as the co-chairman of the Technical Committee on Medical Robotics of the same society.

Alvise Sartori received an M.A. degree in Physics from the University of Oxford in 1978 and a Ph. D. in Geophysics from Imperial College, London, in 1983. He then joined the Central Research Laboratory of Olivetti, where he carried out research on modelling of fluido-dynamic systems and design of digital CMOS integrated circuits. In 1990 he joined IRST, a Research Institute in Trento, Italy, where he was in charge of the VLSI Design Laboratory. Since 1998, he is President and CEO of NeuriCam SpA, Trento, a company he co-founded in 1998, active in the fabless production of chips and systems for computer vision.